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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,466	02/14/2006	Albert John Allen	X16410	8213

25885 7590 07/30/2007  
ELI LILLY & COMPANY  
PATENT DIVISION  
P.O. BOX 6288  
INDIANAPOLIS, IN 46206-6288

EXAMINER
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CLAYTOR, DEIRDRE RENEE

ART UNIT	PAPER NUMBER
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1617

NOTIFICATION DATE	DELIVERY MODE
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07/30/2007

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

## Office Action Summary

**Application No.**

10/568,466

**Applicant(s)**

ALLEN ET AL.

**Examiner**

Renee Claytor

**Art Unit**

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/14/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Priority***

Applicant's claim to priority from PCT/US04/25593, filed 8/25/2004, and U.S. Provisional Application 60/498,146, filed on 8/27/2003, is hereby acknowledged.

### ***Claim Objections***

Claim 1 objected to because of the following informalities: it appears that the claim ends on page 1 after formula I in which it is written "...or a pharmaceutically acceptable salt thereof as sole active agent." However, it appears that Applicant inadvertently did not cross out two formulas on page 7. Appropriate correction is required.

### ***Claim Rejections- 35 U.S.C. § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 4-6 rejected under 35 U.S.C. 103(a) as being unpatentable over Hollander et al. (J Child Neur (2000); 15, 2, page 132-135) in view of Wong et al. (U.S. Patent 6,964,962).

Hollander et al. teach the beneficial treatment of autism spectrum disorders with venlafaxine, which is a potent norepinephrine/serotonin reuptake inhibitor (see entire document). The patients in the study met the Diagnostic and Statistical Manual of Mental Disorders, 4<sup>th</sup> edition (DSM-IV) criteria for pervasive developmental disorders including autism, Asperger's syndrome, and pervasive developmental disorders not otherwise specified (see Methods).

Hollander et al. does not specifically teach atomoxetine (tomoxetine) or the compounds of formula I.

Wong et al. teach that compounds such as tomoxetine, which like venlafaxine (also taught in Col. 6, line 1), is a norepinephrine reuptake inhibitor that is useful in treating central nervous system disorders such as autism (which falls under a pervasive developmental disorder as taught by Hollander et al.) and attention-deficit/hyperactivity disorder (ADHD; Col. 2, lines 6-16 and Col. 9, lines 43-56). The compound can be in the form of pharmaceutically effective salts such as hydrochloride (Col. 6, line 13).

Accordingly, it would be obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Hollander et al., which teaches the treatment of autism spectrum disorders with the norepinephrine reuptake inhibitor venlafaxine, with the teachings of Wong et al. which teach norepinephrine reuptake inhibitors such as tomoxetine as being useful in treating central nervous system disorders, including autism and ADHD. In addition, from the teachings of Wong et al. that the compounds of the invention treat autism and ADHD, it would be obvious that the treatment regimen would treat both disorders if they occur together. One would be motivated to use

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atomoxetine to treat a pervasive developmental disorder, such as autism, with a reasonable expectation of success because of the teachings of Hollander et al. which teaches the usefulness of compounds that inhibit norepinephrine reuptake in treating autism spectrum disorders.

### ***Conclusion***

No claims are allowed.

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

A handwritten signature in black ink, appearing to read 'S. Padmanabhan', with a horizontal line underneath the signature.

SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER